

REMARKS

Status of the Claims

Claims 1, 3-6, 12, and 14-31 are pending in the present application. Claims 3, 6, 12, 14-16, and 24-31 are withdrawn as being directed to a non-elected invention. Claims 2, 7-11, and 13 were previously canceled. In view of the remarks set forth below, reconsideration and allowance of the instant application is respectfully requested.

Statement of the Substance of the Interview

Applicants and Applicants' representative thank the Supervisory Examiner for extending the courtesy of an interview on November 5, 2010.

During the interview, the rejection under 35 U.S.C. § 102(f) was discussed. Applicants' representative submitted that the claims in the instant application and the claims in U.S. Application No. 11/919,579 are directed to different subject matter. Accordingly, Applicants' representative submitted that the Examiner has failed to establish a *prima facie* case under 35 U.S.C. § 102(f). The Supervisory Examiner stated that he reviewed the claims in both applications and agreed that the claims in the instant application and in U.S. Application No. 11/919,579 describe different subject matter. Accordingly, the Supervisory Examiner stated that it is not necessary to respond to the rejection by providing a Declaration under 37 C.F.R. § 1.132.

Notwithstanding the foregoing, the Supervisory Examiner recommended that Applicants explain in the response to the instant Office Action how the claims are different. An explanation of the differences between the inventions claimed in the instant application and in U.S. Application No. 11/919,57 are described herein below.

Non-Statutory Obviousness Type Double Patenting

Claims 1, 3-6, 12, and 14-31 are provisionally rejected on the ground of non-statutory double patenting as allegedly unpatentable over claims 1 and 6 of co-pending U.S. Application No. 11/919,579, *see Office Action*, pages 2-5, item 9.

Applicants note that the instant application was filed on May 1, 2006, which is earlier than the filing date of co-pending U.S. Application No. 11/919,579, *i.e.*, October 30, 2007. According to the MPEP at § 804, if a "provisional" nonstatutory obviousness-type double patenting (ODP)

rejection is the only rejection remaining in the earlier filed of two co-pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. In view of the remarks submitted herewith, Applicants submit that the ODP rejection is the only rejection remaining in the instant, earlier filed application. Accordingly, the Examiner should withdraw the rejection and allow the present application to proceed to allowance.

Issues Under 35 U.S.C. § 102(f)

Claims 1, 3-6, 12, and 14-31 are rejected under 35 U.S.C. § 102(f) because the Applicants allegedly did not invent the claimed subject matter, *see Office Action*, page 5, item 11. According to the Examiner, the instant application and U.S. Application No. 11/919,579 recite claims directed to common subject matter. However, the Examiner states that the instant application and U.S. Application No. 11/919,579 do not have the same inventive entity. That is, the inventors listed on the instant application are Kazahiro MACHIDA, Takashi NAKASHIMA, Yasuhide ARITOKU and Toshio TSUCHIDA. The inventors listed on U.S. Application No. 11/919,579 are Kazahiro MACHIDA and Yasuhide ARITOKU. The Examiner states that Applicants are requested to verify the inventors of the subject matter shared between the two applications.

For the reasons set forth below, Applicants submit that the Examiner has failed to establish a reasonable basis for asserting that the Applicants did not invent the claimed subject matter. As noted during the interview with the Supervisory Examiner, the claims in the instant application and the claims in U.S. Application No. 11/919,579 are directed to different inventions.

Independent claim 1 of U.S. Application No. 11/919,579 is directed to a recombinant microorganism, which has the ability to produce 16 position hydroxyl macrolide compounds represented by formula I, which comprises a) a DNA, which encodes wholly or partially a polypeptide, as described, that participates wholly or partially in the synthesis of macrolide compounds, as represented by formula II and b) a DNA encoding wholly or partially a polypeptide, as described, having 16-position hydroxylating enzyme activity with respect to the macrolide compounds represented by formula II.

Independent claims 18-20 of U.S. Application No. 11/919,579 are directed to a variant DNA comprising the continuous nucleotide sequence of nucleotides 1322 to 2548 of sequence 2, which further comprises specifically described modified sites.

Claim 5 of the instant application is directed to a transformant, which is arguably the same as a recombinant microorganism. However, the transformant of claim 5 comprises a recombinant plasmid carrying a DNA encoding for a protein that participates in the biological transformation of a macrolide compound represented by formula I, (which is encompassed by formula II of U.S. Application No. 11/919,579) into a 16-position hydroxyl macrolide compound represented by formula II, (which is encompassed by formula I of U.S. Application No. 11/919,579). Accordingly, independent claim 1 of U.S. Application No. 11/919,579 comprises two types of DNA, while claim 5 of the instant application comprises one type of DNA. Therefore, for at least this reason the claims in the two applications are not directed to common subject matter.

Further, none of the DNA claims in the instant application describe the modified sites specified in independent DNA claims 18-20 of U.S. Application No. 11/919,579. Accordingly, for at least this reason, the DNA claims in the two applications are also not directed to common subject matter. Moreover, the Examiner has failed to provide any reason as to why she believes that the inventive entities should be identical between the two co-pending applications, given that the claimed inventions are different. Accordingly, the Examiner has provided no basis to doubt the inventive entities of the instant application and U. S. Application No. 11/919,579.

Notwithstanding the foregoing, Applicants confirm that the inventive entity in the instant application and in U.S. Application No. 11/919,579 is correct. In particular, Applicants submit that Mr. Tsuchida and Mr. Aritoku conceived of the invention described in claims 12 to 16 in part, and the subject matter described in examples 13 and 14 in part, of the instant application. Mr. Machida and Mr. Nakashima conceived part or all of the inventions as claimed in the instant application including DNA encoding protein having 16 position hydroxylating enzymatic activity.

Applicants further confirm that Mr. Machida and Mr. Aritoku conceived of the invention as claimed in U.S. Application No. 11/919,579.

As described above, the invention claimed in U.S. Application No. 11/919,579, utilizes the instantly claimed invention, which is directed to DNA encoding protein having 16 position hydroxylating enzymatic activity. That is, the claimed subject matter in U.S. Application No. 11/919,579 includes claims directed to a recombinant microorganism, which includes the DNA claimed in the instant application and a DNA encoding a polypeptide involved in the biosynthesis of a macrolide compound pladienolide, which does not have a hydroxy group at the 16 position.

Mr. Machida and Mr. Aritoku conceived of the invention as claimed in U.S. Application No. 11/919,579, which is directed to a recombinant microorganism (or transformant) by utilizing the DNA encoding protein having a 16 position hydroxylating enzymatic activity, which was invented by Mr. Machida and Mr. Nakashima in the instant application. Accordingly, the inventors in the instant application and the co-pending application are properly named. The Examiner has provided no basis to assert otherwise.

In view of the foregoing, Applicants believe the rejection under 35 U.S.C. § 102(f) is improper. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the remarks submitted herewith, Applicants believe the instant application is in condition for allowance. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact L. T. Parker, Ph.D., Registration No. 46,046, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 

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